Atty. Docket E-5-2

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### REMARKS

Re. the Office Action

As set forth in the Office Action, Claims 26-47 were examined. Of these claims,

- (i) Claims 42, 43 and 47 are rejected under 35 U.S.C. 112, first paragraph as containing limitations that lack support in the originally filed specification in that the location pointed out in the Remarks of a previous reply is not consistent with the claimed limitations;
- (ii) Claims 44-46 are rejected under 112 U.S.C. second paragraph as being indefinite in that the claims relate to a flexible embodiment while the shaft is defined as rigid; also, in Claim 45, the active member has not been previously set forth;
- (iii) Claims 26-34, 36, 38, 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,674,499 ("Pao"), in that Pao discloses an electrosurgical instrument having a shaft with a rigid distal end portion, the shaft including an active and a return electrode, with a fluid delivery and aspiration features, and with similar uses;
- (iv) Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pao in view of U.S. Patent no. 4,301,802 ("Poler"), in that the fluid lumen in Pao is within the first electrode terminal, and Poler discloses a similar device but includes a fluid delivery lumen about the shaft of the first electrode and between the shaft and the return electrode; hence, it would have been obvious to form a fluid lumen about the shaft of Pao's to better distribute fluid between the electrodes;
- (v) Claims 37 and 39 would be allowable if rewritten to overcome the 35 U.S.C. 112, second paragraph rejection, supra, and to include the limitations of the base and intervening claims.

#### Re. the Amendments

The status of related applications in the specification is updated, as requested above.

The claims are been amended to better define the Applicant's apparatus, and to include new Claims 48-57. In particular,

Claim 48 is based on the disclosure of and PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, now U.S. Patent No. 5,697,909,

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which is incorporated by reference into the present specification, and wherein at a page 17, lines 24-25 and Fig. 2 it is disclosed that L1, the spacing between the active and return electrode, is in the range of 0.5 to 25 mm;

Claim 49 is based on page 7, lines 21-23 of the present disclosure where it is stated that a conductive gel is placed between the electrode terminals and the tissue; and

Claim 50 is based on, for example, the system of Fig. 3 of the present disclosure that indicates a controller (28), and the description at page 19, line 16 that reference a controller. Similar comments apply to Claims 51-57.

In view of amendments to the specification and the claims, and also in view of the following remarks, reconsideration and the allowance of the application is respectfully requested.

## Re. The rejection of Claims 42, 43 and 47 under 35 U.S.C. 112, first paragraph on the basis that the claimed matter lacked support in the specification

Claims 42 and 47 are cancelled and Claim 43 is amended to better define the claimed apparatus, as set for the therein. Support for the amendments can be found, for example, at page 13, lines 7-11. Accordingly, withdrawal of the rejection and reconsideration of the claims are respectfully requested.

# Re. The rejection of Claims 44-46 under 112 U.S.C. second paragraph as being indefinite in that the distal tip of the shaft is specified to be rigid, whereas the claims specify a material that can be deflected

Claims 44 is amended to specify that the shaft is bent relative to the longitudinal axis of the shaft, as the tip, notwithstanding its rigidity is nevertheless bendable as is indicated for example in Fig. 4. Claims 45 and 46 are amended to depend from Claim 26, based on, for example, the embodiment of Fig. 8A and the specification at page 29, lines 5-11.

Accordingly, in view of the Remarks herein regarding Claim 26, withdrawal of the rejection and reconsideration of the claims are respectfully requested.

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Re. The rejection of Claims 26-34, 36, 38, 40-41 under 35 U.S.C. 102(b) as being anticipated by Pao

Claim 26 is amended to better define the Applicant's apparatus, by specifying that both the active and return electrodes are disposed on the shaft, and that the active electrode is disposed on the distal tip portion of the shaft where it is spaced proximally away from the return electrode, such that the axial spacing between the active and return electrodes is sufficient to prevent both electrodes from simultaneously contacting the body surface during said treatment. Additionally, as set forth in the claims, electrical conductors are provided in the shaft for connecting the electrodes across a high-frequency voltage supply, to conduct a high-frequency voltage supply across the electrodes that is sufficient to volumetrically remove at least a portion of the body structure.

Thus as amended, Claim 26 and its dependent claims 27-34, 36, 38, 40-41 are not anticipate by Pao because, *inter alia*,:

- i) Pao does not teach an apparatus wherein an active electrode is disposed on the distal tip of a shaft, distal from the return electrode on the shaft, wherein the axial spacing between the active and return electrodes on the shaft is sufficient to prevent both electrodes from simultaneously contacting the body surface during the treating;
- ii) Pao does not teach an <u>electrical conductor disposed through a shaft for connecting the active electrode</u>, at the tip of the shaft, across a high-frequency voltage supply. In this regard it is noted that the Applicant active electrode is disposed at the distal tip of the shaft and thus does not extend through the shaft as in Pao'; and
- iii) Pao does not teach an apparatus that specifies a high-frequency voltage supply across the electrodes sufficient to volumetrically remove at least a portion of the body structure. In this regard it is noted that Pao's device is designed for scleral marking, and there is no teaching, suggestion or indication that this device is intended or capable of volumetrically removing tissue from a body structure.

Regarding the axial spacing between the electrodes on the shaft as set forth in the claims, Pao teaches a spacing the range of 0.6 mm to 1.0 mm, preferably 0.7 mm to 0.8 mm, for the purpose of ensuring that both electrodes are brought in contact with the tissue (see Pao at Col. 2, line 37-40, and Col. 2, line 58-64. Such a spacing is contrary to the Applicant's apparatus

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which requires that the <u>axial spacing between the active and return electrodes on the shaft is</u> sufficient to prevent both electrodes from simultaneously contacting the body surface during the treating; in one embodiment the spacing is greater than about 1.0 mm.

Accordingly, in view of the failure of Pao to teach (or indeed to suggest) the Applicant's claimed apparatus, therefore withdrawal of the rejection and reconsideration of the claims are respectfully requested.

## Re. The rejection of Claim 35 under 35 U.S.C. 103(a) as being unpatentable over Pao in view of Poler

In rejecting Claim 35 under this heading, the Office Action cited Poler for teaching a fluid delivery lumen located about the shaft of the active electrode, instead of within the active electrode as indicated in Pao, and thus in view of Poler over Pao, the Applicant's device is unpatentable.

As noted, above, Pao does not disclose several aspects of the Applicant's claimed device including an <u>axial spacing between the active and return electrodes on the shaft is sufficient to prevent both electrodes from simultaneously contacting the body surface during the treating.</u>

Hence in view of the deficiencies in Pao, which are not rectified by Poler, the Applicant's claims are patentable, notwithstanding the comments in the Office Action.

### Re. The allowability of Claims 37 and 39

The Applicants acknowledge with thanks the allowability of Claims 37 and 39. However in view of the present RCE, the Applicants request that that rewriting of these claims be postponed at least until this RCE has been considered.

### **SUMMARY**

The Applicant's claims are patentable over the cited references and, in view of the amendment and remarks herein, reconsideration and allowance are respectfully requested. If an issue remains the can be resolved by a telephone conference, please contact the undersigned at telephone (408) 735-6486.

Sincerely,

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